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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/551,262	09/28/2005	Richard Markoli	26993U	3360
20529 7590 02/26/2007 NATH & ASSOCIATES 112 South West Street Alexandria, VA 22314			EXAMINER CHEN, VICTORIA W	
			ART UNIT	PAPER NUMBER
			3739	
SHORTENED STATUTORY PERIOD OF RESPONSE		MAIL DATE	DELIVERY MODE	
3 MONTHS		02/26/2007	PAPER	

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary

Application No.

10/551,262

Applicant(s)

MARKOLL, RICHARD

Examiner

Victoria W. Chen

Art Unit

3739

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 28 September 2005.
2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-15 is/are pending in the application.
4a) Of the above claim(s) _____ is/are withdrawn from consideration.
5) ☐ Claim(s) _____ is/are allowed.
6) ☒ Claim(s) 1-15 is/are rejected.
7) ☐ Claim(s) _____ is/are objected to.
8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
10) ☒ The drawing(s) filed on 28 September 2005 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date 1/10/06
4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____

DETAILED ACTION

Information Disclosure Statement

The listing of references in the specification is not a proper information disclosure statement. 37 CFR 1.98(b) requires a list of all patents, publications, or other information submitted for consideration by the Office, and MPEP § 609.04(a) states, "the list may not be incorporated into the specification but must be submitted in a separate paper." Therefore, unless the references have been cited by the examiner on form PTO-892, they have not been considered.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 7-15 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 7 provides for the preparation of a pharmaceutical composition comprising botulinum toxin, but, since the claim does not set forth any steps involved in the method/process, it is unclear what method/process applicant is intending to encompass. A claim is indefinite where it merely recites a use without any active, positive steps delimiting how this use is actually practiced.

Claims 7-15 are rejected under 35 U.S.C. 101 because the claimed recitation of a use, without setting forth any steps involved in the process, results in an improper definition of a process, i.e., results in a claim which is not a proper process claim under 35 U.S.C. 101. See for

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example *Ex parte Dunki*, 153 USPQ 678 (Bd.App. 1967) and *Clinical Products, Ltd. v. Brenner*, 255 F. Supp. 131, 149 USPQ 475 (D.D.C. 1966).

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1, 2 and 6 are rejected under 35 U.S.C. 102(e) as being anticipated by Ostrow et al. (US Pat No. 6443883B1).

Regarding claim 1, Ostrow discloses a treatment for osteoporosis comprising exposing a patient to electromagnetic signals generated by pulsating, impulse modulated direct current, where the frequency is 1 to 30 Hz and the field strength is 1 to 20 G [col. 18, ll. 16-18, 29-31].

Regarding claim 2, Ostrow discloses the modulation form is quasi-rectangular [col. 18, ln. 16].

Regarding claim 6, Ostrow discloses the pulses are modulated [col. 13, ll. 55-58].

Claims 1, 3 and 6 are rejected under 35 U.S.C. 102(e) as being anticipated by Becker et al. (USPGPUB 2004/0077921 A1).

Regarding claim 1, Becker discloses a treatment for osteoporosis comprising exposing a patient to electromagnetic signals generated by pulsating, impulse modulated direct current, where the frequency is 1 to 30 Hz and the field strength is 1 to 20 G [see claim 1].

Regarding claim 3, Becker discloses the frequency is approximately between 5-15 Hz [see claim 3].

Regarding claim 6, Becker discloses that the pulses are modulated [see claim 8].

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 7, 8 and 12-15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ostrow in view of Aoki et al. (US Pat No 6464986 B1).

Ostrow discloses the electromagnetic stimulation as claimed except fails to disclose the use of Botulinum toxin in conjunction with the stimulation. Aoki teaches the use of Botulinum toxin for the treatment of pain caused by osteoporosis [col. 24, ll. 15-30]. Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention to use Botulinum toxin in conjunction with electromagnetic stimulation for the treatment of osteoporosis in order to treat the pain during electromagnetic treatment.

Regarding claims 8 and 12, see rejections of claims 2 and 6 above.

Regarding claims 13 and 14, Aoki teaches the use of 50-200U of Botulinum toxin Type A for treatment of pain [col. 24, ll. 20-22].

Regarding claim 15, Aoki teaches the use of 50-400U of Botulinum toxin Type B [col. 9, ll. 47-48].

Claims 7, 9, 12-15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Becker in view of Aoki et al. (US Pat No 6464986 B1).

Becker discloses the electromagnetic stimulation as claimed except fails to disclose the use of Botulinum toxin in conjunction with the stimulation. Aoki teaches the use of Botulinum toxin for the treatment of pain caused by osteoporosis [col. 24, ll. 15-30]. Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention to use Botulinum toxin in conjunction with electromagnetic stimulation for the treatment of osteoporosis in order to treat the pain during electromagnetic treatment.

Regarding claims 9 and 12, see rejections of claims 3 and 6 above.

Regarding claims 13 and 14, Aoki teaches the use of 50-200U of Botulinum toxin Type A for treatment of pain [col. 24, ll. 20-22].

Regarding claim 15, Aoki teaches the use of 50-400U of Botulinum toxin Type B [col. 9, ll. 47-48].

Claims 1-5 are rejected under 35 U.S.C. 103(a) as being unpatentable over Waltonen et al. (US Pat No 4674482).

Regarding claim 1, Waltonen discloses a treatment for tissue comprising exposing a patient to electromagnetic signals generated by pulsating, impulse modulated direct current with a range of frequency and field strength, however does not specifically disclose the range of between 1-30 Hz and 1-20 G. Waltonen does disclose a range of frequencies between 1-100 Hz [col. 3, ll. 36-40] and a range of field strength between 4-22 G [col. 3, ll. 56-57]. Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention to find the best set of parameters within those ranges for the treatment of tissue, specifically osteoporosis.

Regarding claim 2, Waltonen teaches the modulation form is quasirectangular [col. 5, ll. 11-15].

Regarding claims 3-5, see rejection of claim 1 under Waltonen.

Claims 7-11 and 13-15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Waltonen in view of Aoki et al. (US Pat No 6464986 B1).

Waltonen discloses the electromagnetic stimulation as claimed except fails to disclose the use of Botulinum toxin in conjunction with the stimulation. Aoki teaches the use of Botulinum toxin for the treatment of pain caused by osteoporosis [col. 24, ll. 15-30]. Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention to use Botulinum toxin in conjunction with electromagnetic stimulation for the treatment of osteoporosis in order to treat the pain during electromagnetic treatment.

Regarding claims 8-11, see rejections of claims 2-5 under Waltonen above.

Regarding claims 13 and 14, Aoki teaches the use of 50-200U of Botulinum toxin Type A for treatment of pain [col. 24, ll. 20-22].

Regarding claim 15, Aoki teaches the use of 50-400U of Botulinum toxin Type B [col. 9, ll. 47-48].

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

US 20020165583 A1 US-PGPUB Tepper, John C. et al. PEMF stimulator for
treating osteoporosis and stimulating tissue growth

US 6839595 B2 USPAT Tepper, John C. et al. PEMF stimulator for treating osteoporosis
and stimulating tissue growth

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US 5100373 A USPAT Liboff; Abraham R. et al. Techniques for controlling osteoporosis
using non-invasive magnetic fields

US 5267939 A USPAT Liboff; Abraham R. et al. Techniques for controlling osteoporosis
using non-invasive magnetic fields

US 20020176872 A1 US-PGPUB Aoki, Kei Roger et al. Pain treatment by
peripheral administration of a neurotoxin

US 20040073260 A1 US-PGPUB Brighton, Carl T. Regulation of type II collagen gene
expression using specific and selective electrical and electromagnetic signals

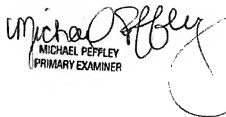
US 6899667 B2 USPAT Becker; Paul F. et al. Method and apparatus for the treatment of
physical and mental disorders with low frequency, low flux density magnetic fields

Any inquiry concerning this communication or earlier communications from the
examiner should be directed to Victoria W. Chen whose telephone number is (571) 272-3356.
The examiner can normally be reached on M-F 8:30-5.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's
supervisor, Linda Dvorak can be reached on (571) 272-4764. The fax phone number for the
organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

VWC
2/16/07


MICHAEL PEPPLEY
PRIMARY EXAMINER